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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,662	11/30/2000	Mark A. Hayes ¹	31737PCTUSA	6662

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EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,662

Applicant(s)

HAYES ET AL.

Examiner

Kaj Olsen

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6, 7 is/are allowed.
- 6) ☐ Claim(s) 5 and 8-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other:

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It improperly identifies the international filing date for the application. The declaration lists a date of July 29, 1999 whereas the International Bureau of WIPO identifies the date as being June 11, 1999.

Double Patenting

2. Applicant is advised that should claims 9 and 10 be found allowable, claims 12 and 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "5" has been used to designate an electrode, a channel entrance and a buffer solution (see p. 9, lines 19-30). Reference character "6" has also been utilized to designate an electrode and a channel entrance. A proposed drawing correction or corrected drawings are

Art Unit: 1753

required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 5 appears to the further limit limitation (e) of claim 1, which specifies that a flow rate is to be applied that is equal and opposite that of the electrophoretic migration. However, it is unclear to the examiner from reading the specification how electroosmosis (i.e. the subject of claim 5) could be the means for providing a flow rate opposite to the electrophoretic migration. As evidentiary reference Manz et al (J. Micromech. Microeng. 4 (1994), pp. 257-265) demonstrates, both electrophoresis and electroosmosis rely on the movement of particles in a capillary tube via an externally applied voltage. Because applicant is applying a voltage for inducing electrophoretic migration (e.g. step (d) of claim 1), how can the applicant adjust an opposite flow of fluid by also using an applied voltage for inducing electroosmosis? An additional voltage source in the constrained fluid pathway would appear to only add or subtract from the electrophoretic voltage applied to the electrodes. Thereby any attempt to adjust the electroosmotic flow with an additional voltage

Art Unit: 1753

source would then cause the electrophoretic flow to either increase or decrease. It doesn't appear that the applicant could also utilize the same voltage source to provide both electrophoretic migration and electroosmotic flow that is opposite the electrophoretic migration. This is because any attempt to "adjust" the electroosmotic flow (as step (e) of claim 1 requires) would simultaneously increase or decrease electrophoretic mobility. The specification doesn't appear to specify any embodiment of the invention demonstrating the use of electroosmosis as the means for adjusting flow rate. The specification explicitly demonstrates the use of pressure (claim 6), which the examiner considers enabling. Clarification as to how one possessing ordinary skill in the art would be able to simultaneously provide (a) an applied voltage for promoting electrophoretic migration, (b) adjustable electroosmotic flow that is equal and opposite to the electrophoretic migration, and (c) where movement of the specific sample component ceases.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 8-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/04,547 (hereafter "WO '547").

8. With respect to claim 8, WO '547 discloses an electrophoretic apparatus that comprises at least one fluid constrained pathway (30B, 32B) having an inlet and an electrode 51 mounted at

the inlet of the constrained fluid pathway and is entirely external to the constrained fluid pathway (fig. 6 and p. 15, lines 12-29). WO '547 also discloses a power supply 46B (p. 9, lines 11-21).

9. With respect to claims 9 and 12, see abstract.

10. With respect to claims 10 and 13, the microfluidic channels of WO '547 read on the applicant's term "capillary" giving the claim language its broadest reasonable interpretation, because the channels are being utilized for the performance of capillary electrophoresis.

11. With respect to claim 11, see p. 15, lines 27-29.

12. With respect to claim 14, see p. 11, lines 19-28.

13. With respect to claim 15, channels 30B and 32B form an injection fluid pathway having an electrode 51 mounted at the inlet of the pathway (fig. 6 and p. 15, lines 12-29). WO '547 also discloses a separation channel 34B having an electrode 50 mounted at the inlet of said pathway and further discloses a means for regulating the bulk flow within the channels (fig. 6 and p. 16, lines 16-29).

14. With respect to claim 16, see abstract.

15. With respect to claim 17, the microfluidic channels of WO '547 read on the applicant's term "capillary" giving the claim language its broadest reasonable interpretation, because the channels are being utilized for the performance of capillary electrophoresis.

Allowable Subject Matter

16. Claims 1-4, 6 and 7 are allowed.

17. The following is an examiner's statement of reasons for allowance: the prior art does not disclose nor render obvious a method for controlling the movement of fluid where

Art Unit: 1753

electrophoretic migration is combined with a simultaneous adjustment of the flow rate to be equal and opposite to the electrophoretic migration where the specific sample component ceases movement. Although the PCT search report indicates that references Ivory (USP 5,200,050) and WO 96/27,793 are "X" references for claim 1, the examiner does not believe either reference teaches nor renders obvious the claimed subject matter of claim 1. In particular, Ivory teaches that at some point the electrophoretic mobility and counterflow velocity balance each other (as is conventional in isoelectric focusing). However, claim 1 requires that the flow rate be adjusted to be equal and opposite the electrophoretic flow. The samples of Ivory merely migrate until the two forces above are in balance in contrast to the specific language of claim 1. With respect to WO '793, the examiner cannot find anything in this cited reference to suggest the allowable combination of limitations of claim 1 highlighted above by the examiner and claim 1 is deemed free of the teaching of WO '793.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Keely and Singh teach techniques relying on the application of both pressure and voltage to control sample movement.

Art Unit: 1753

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Kaj K. Olsen
Patent Examiner
AU 1753
August 11, 2003